REMARKS

On page 2 of the Office Action, the Examiner contends that the Statement under 37 C.F.R § 1.821 is defective since it does not set forth that the submission does not contain new matter.

Accordingly, Applicants submit herewith a new Statement setting forth that the submission does not contain new matter.

On page 3 of the Office Action, the Examiner maintains the rejection of Claims 31-33 and 35 under 35 U.S.C. § 112, first paragraph on the basis that, while the specification is enabling for a hydroxylated triple helical protein, wherein the protein is a collagen, such is not enabling for the broad scope of polypeptides encompassed by the claims because the specification does not teach how any protein other than a collagen can be used therapeutically.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

The Examiner is requested to note that Claims 31-33 are directed to a triple helix containing protein *per se*. These claims do not require the protein to be suitable for a therapeutic application. Applicants respectfully submit that it is clear from the specification that the hydroxylated triple helical protein of the invention is capable of being used in applications other than therapeutic applications.

For example, at page 1, line 33, and page 2, line 9, of the present specification, it indicates that the protein of the invention can include exogenous biologically active domains to provide additional protein function and other characteristic. Further, at page 8, lines 34-36 of the present specification, it is taught that the product-encoding nucleotide sequences may include a sequence(s) encoding secretion signal. In addition,

Example 7 of the present application describes the synthesis of a hydroxylated triple helical protein wherein a Flag epitope is linked to a "SYN-C3" triple helical forming sequence. The presence of a Flag epitope allows for easy separation of the hydroxylated triple helical protein through immunochromatography. Thus, since Claims 31-33 are not limited to a therapeutic application, it is clear that these claims are enabled by the present specification.

With regard to Claim 35, in order to expedite allowance thereof, Applicants hereby amend Claim 35 in the same manner as Claim 34 (Claim 34 has not been included in this rejection). Thus, the Examiner's rejection of Claim 35 has been rendered moot.

Accordingly, Applicants respectfully submit that the claims are enabled by the present specification, and thus request withdrawal of the Examiner's rejection.

On page 4 of the Office Action, the Examiner maintains the rejection of Claims 31-33 under 35 U.S.C. § 102(b) as being anticipated by Fields et al.

The Examiner notes that Applicants have amended Claim 31 such that the claimed protein comprises one polypeptide or peptide domain which is heterologous to collagen proteins, and which does not comprises a triple helical forming repeating sequence, and that Applicants argue that Fields et al does not teach such a polypeptide. However, the Examiner contends that Figure 1 of Fields et al shows a triple helical protein according to the claimed invention, comprising the peptide sequence "lys-lys-tyr-gly" which meets the limitation of a peptide domain which is heterologous to collagen proteins and which does not comprise a triple helical forming repeating sequence.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Fields et al describes the solid phase synthesis of aligned branched, branched triple helical peptides. As the Examiner notes, these proteins comprise the peptide sequence "lys-lys-tyr-gly". However, in Fields et al this sequence is covalently linked to three triple helical sequences via spacer groups "Ahx". "Ahx" is 6-aminohexanoic acid, which is not an alpha amino acid residue. Thus, the peptide of Fields et al can not be produced recombinantly as claimed in the present application.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in Fields et al, and thus request withdrawal if the Examiner's rejection.

On page 6 of the Office Action, the Examiner maintains the rejection of Claims 31-35 under 35 U.S.C. § 102(e) as being anticipated by St. Pierre et al.

Specifically, the Examiner notes Applicants' argument that St. Pierre et al does not teach a triple helical protein that contains at least on heterologous domain. However, the Examiner contends that in Formula A (column 3), St. Pierre describes a hydroxylated triple helical protein according to the limitations of Claim 31, wherein the protein comprises a "polymer", and at column 5, lines 60, St. Pierre et al teaches that this polymer can be a peptide selected from polyglutamic acid, polyaspartic acid and polylysine, which meets the limitations of at least one peptide domain which is heterologous to collagen proteins and which does not comprise a triple helical forming repeating sequence.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

St Pierre is similar to that of Fields et al in that the peptides therein are described as being synthesised by a chemical synthesis protocol, as opposed to being recombinantly produced, as claimed in the present application.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in St. Pierre et al, and thus request withdrawal if the Examiner's rejection.

On page 5 of the Office Action, the Examiner maintains the rejection of Claims 31-32 under 35 U.S.C. § 102(b) as being anticipated by any one of the recited Swiss-Prot database entries. The Examiner notes Applicants' arguments that the cited database entries are silent with regard to a hydroxylated triple helical protein that contains at least one heterologous domain as recited in amended Claim 31. However, the Examiner contends that the polypeptide or peptide domain of Claim 31 is limited to being heterologous to collagen and not heterologous to the protein comprising the triple helical domain. Further, the Examiner contends that the collagen repeat domain, P02745 comprises a sequence unique to a complement protein, P35247 and P07714 comprise a sequence unique to pulmonary surfactant proteins, P21757 comprises a sequence unique to macrophage scavenger receptor proteins, P23805 comprises a sequence unique to conglutinin proteins and P11226 comprises a sequence unique to mannose binding protein proteins, each of which are heterologous to collagen.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

The Swiss-Prot references are all directed to naturally occurring sequences. Therefore, they are not synthetic

recombinant, as claimed in the present application. Moreover, there is no disclosure in the Swiss-Prot references of a synthetic recombinant method by which the proteins of the Swiss-Prot references can be synthesized to produce the proteins described therein, and in particular so that the proteins retain their biological function and other useful characteristics.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in the Swiss-Prot references, and thus request withdrawal if the Examiner's rejection.

On page 6 of the Office Action, the Examiner issues a new rejection of Claims 31-35 under 35 U.S.C. § 112, first paragraph.

Specifically, the Examiner contends that the amended claims contain new matter, i.e., Claim 31 has been amended such that n in the sequence $(GlyXY)_n$ is limited to being 2 to 1500. However, the Examiner contends that the only reference to 2 to 1500 in the specification is in reference to $(GlyXY)_i$ comprised within domain Z, whereas in contrast the term $(GlyXY)_n$ is originally comprised within domain A. The Examiner can find no statement in the specification which would lead one skilled to believe that the limitations of $(GlyXY)_i$ are the same as those of $(GlyXY)_n$.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

The Examiner's attention is directed to page 7, lines 3-13, preferably line 10, of the specification, which indicates that "...n is in the range of 2 to 1500 (preferably 10 to 350)..."

The Examiner also notes that Claim 31 has been amended such that the descriptions of terms B and C includes the *proviso* "at

least one of m and o is 1". However, the Examiner contends that he can not find support for such in the specification.

Applicants respectfully submit that the formula given in the present claims is not a laundry list or shotgun disclosure of a very large number of alternatives. Rather, the formula in its broadest sense, is a shorthand for alternatives that the skilled person can readily write out by hand, e.g.,

A-B-[Z]-C-D, A-[Z]-C-D, A-[Z]-C, A-B-Z, A-[Z]-C-D, B-[Z]-C-D, B-[Z]-C, A-Z, B-[Z]-C-D, A-[Z]-D, B-Z, A-B-[Z]-C, B-[Z]-D, Z-C-D, Z-C, Z-D

Applicants have not included the case where 1, m, n and o are all zero as the claimed invention as this would simply cover collagen.

As taught at page 2, lines 4-9 of the specification, the synthetic collagen [i.e., protein] may include one exogenous biologically active domain. This supports the requirement that at least one of 1, m, n or o is 1. At page 7, lines 12-13 of the present specification, it states that the "triple helical proteins may include non-collagenous, non-triple helical domains at the amino and/or carboxy terminal ends or **elsewhere**." Thus, the skilled person would see this statement as providing a blaze mark for 1 or p being 1 or both 1 and p being 1. The reference to "elsewhere", when read in conjunction with the formula itself also provides a blaze mark to m or n being 1, or both m and n being 1. A similar blaze mark appears at page 8, lines 17-30, which refers to the possibility of polypeptide domains at A, B, C and/or D.

Accordingly, Applicants respectfully submit that claims are supported by the present specification, and thus request withdrawal of the Examiner's rejection.

In view of the amendments to the claims, and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

Gordon Kit
Registration No. 30,764

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

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